KONFORMITÄTSERKLÄRUNG / *DECLARATION OF CONFORMITY*

Name und Adresse der Firma / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Deutschland / *Germany* *SRN: DE-MF-000007705*

Wir erklären in alleiniger Verantwortung, dass / *We declare under our sole responsibility that*

das Medizinprodukt / *the medical device*	**Palapress vario**
Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikelliste siehe Anhang / *List of Articles see Annex*
EMDN-Nummer / *EMDN-Code* GMDN-Nummer / *GMDN code* UMDNS-Nummer / *UMDNS code* Basis-UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
der Klasse / *of class*	IIa
nach Regel / *according to rule*	5-3, 19-3 nach Anhang VIII der Medizinprodukte-Verordnung, 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Zahnheilkunde – Kunststoffe – Teil 1: Prothesenkunststoffe / *Dentistry – Base polymers – Part 1: Denture base polymers* Weitere angewandte Normen siehe Version 2 der Technischen Dokumentation von Product Palapress vario / *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 und Kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / *Registration No.*	HZ 1198082-1
Versionsnummer / *Version number*	02
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023 Ort, Datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Name und Funktion / *Name and function*

Diese Konformitätserklärung ist gültig für 2 Jahre in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der produzierten Medizinprodukte / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

DECLARACIÓN DE CONFORMIDAD / *DECLARATION OF CONFORMITY*

Nombre y dirección de la empresa / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Alemania / *Germany* *SRN: DE-MF-000007705*

Declaramos bajo nuestra exclusiva responsabilidad que / *We declare under our sole responsibility that*

el producto sanitario / *the medical device*	**Palapress vario**
Nombre, tipo o modelo, lote o número de serie, posiblemente fuentes y número de elementos / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de artículos en el Anexo / *List of Articles see Annex*
Código EMDN / *EMDN-Code* Código GMDN / *GMDN code* Código UMDNS / *UMDNS code* UDI-DI básico / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	5-3, 19-3 de acuerdo con el Anexo VIII del Reglamento sobre productos sanitarios 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

cumple todas las disposiciones del Reglamento sobre productos sanitarios 2017/745 que se le aplican. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Normas armonizadas, normas nacionales u otros documentos normativos que se aplican / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Para otras normas aplicadas consulte la documentación técnica del producto Palapress vario, versión 2 *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de registro / *Registration number*:	HZ 1198082-1
Número de versión / *Version number*	02
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023 Lugar, fecha / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nombre y cargo / *Name and function*

La presente declaración de conformidad tendrá una validez de 2 años según la documentación emitida para el correspondiente lote de productos fabricados. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

DÉCLARATION DE CONFORMITÉ / *DECLARATION OF CONFORMITY*

Nom et adresse de la société / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Allemagne / *Germany* *SRN: DE-MF-000007705*

Nous déclarons sous notre seule responsabilité que / *We declare under our sole responsibility that*

le dispositif médical / *the medical device*	**Palapress vario**
Nom, type ou modèle, numéro de lot ou de série, éventuellement sources et nombre d'articles / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste des articles voir l'Annexe / *List of Articles see Annex*
Code EMDN / *EMDN-Code* Code GMDN / *GMDN code* Code UMDNS / *UMDNS code* UDI-DI de base / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
de classe / *of class*	IIa
selon la règle / *according to rule*	5-3, 19-3 conformément à l'Annexe VIII du Règlement des Dispositifs Médicaux 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

répond à toutes les dispositions du Règlement des Dispositifs Médicaux 2017/745 qui lui sont applicables. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Application de normes harmonisées, de normes nationales ou d'autres documents normatifs / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Autres normes appliquées voir Documentation technique du produit Palapress vario, version 2 *Further Applied standards see Technical Documentation of Product* Palapress vario*, Version 2*
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	Règlement relatif aux dispositifs médicaux 2017/745 Annexe IX, Chapitre I, Paragraphes 2 et 3 et Chapitre III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organisme notifié / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Allemagne CE 0197
Numéro d'enregistrement / *Registration number*:	HZ 1198082-1
Numéro de version / *Version number*	02
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023 Lieu, date / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nom et fonction / *Name and function*

Cette déclaration de conformité est valable 2 ans en relation avec les documents de libération pour le lot respectif des dispositifs médicaux fabriqués / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / *DECLARATION OF CONFORMITY*

Επωνυμία και διεύθυνση εταιρείας / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Γερμανία / *Germany* *SRN: DE-MF-000007705*

Δηλώνουμε με δική μας ευθύνη ότι / *We declare under our sole responsibility that*

το ιατροτεχνολογικό προϊόν / *the medical device*	**Palapress vario**
Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός σειράς, πιθανές πηγές και αριθμός ειδών / *Name, type or model, batch or serial number, possibly sources and number of items*	Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*
Κωδικός EMDN / *EMDN-Code* Κωδικός GMDN / *GMDN code* Κωδικός UMDNS / *UMDNS code* Βασικό UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
κλάσης / *of class*	IIa
σύμφωνα με τον κανόνα / *according to rule*	5-3, 19-3 σύμφωνα με το Παράρτημα VIII του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα / *according to Annex VIII of Medical Device Regulation 2017/745*

πληροί όλες τις ισχύουσες διατάξεις του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Εφαρμοζόμενα εναρμονισμένα πρότυπα, εθνικά πρότυπα ή άλλα κανονιστικά έγγραφα / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του Προϊόντος Palapress vario, έκδοση 2 *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με / *Conformity assessment procedure acc. to*	Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα, Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Κοινοποιημένος οργανισμός / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Γερμανία CE 0197
Αριθμός καταχώρησης / *Registration number*:	HZ 1198082-1
Αριθμός έκδοσης / *Version number*	02
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	29.03.2022
Hanau,	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Τόπος, ημερομηνία / *Place,* Jan 4, 2023 *date*	Ονοματεπώνυμο και τίτλος / *Name and function*

Αυτή η δήλωση συμμόρφωσης ισχύει για 2 χρόνια σε σχέση με τα έγγραφα κυκλοφορίας για την αντίστοιχη παρτίδα των παραγόμενων προϊόντων. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

Naziv i adresa tvrtke / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Njemačka / *Germany* *SRN: DE-MF-000007705*

Izjavljujemo pod punom odgovornošću da / *We declare under our sole responsibility that*

medicinski proizvod / *the medical device*	**Palapress vario**
Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / *Name, type or model, batch or serial number, possibly sources and number of items*	Popis artikala, pogledajte Dodatak / *List of Articles see Annex*
šifra EMDN / *EMDN-Code* šifra GMDN / *GMDN code* šifra UMDNS / *UMDNS code* osnovni UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
klase / *of class*	IIa
u skladu s pravilom / *according to rule*	5-3, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745*

ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Palapress vario, verzija 2 *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Postupak procjene usklađenosti prema / *Conformity assessment procedure acc. to*	Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Obaviješteno tijelo / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka CE 0197
Registracijski broj / *Registration number*:	HZ 1198082-1
Broj verzije / *Version number*	02
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Mjesto, datum / *Place, date*	Ime i funkcija / *Name and function*

Ova Izjava o usklađenosti valjana je 2 godine u odnosu na dokumente o izdanju za odgovarajuće serije proizvedenih umedicinskih proizvoda. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

DICHIARAZIONE DI CONFORMITÀ / *DECLARATION OF CONFORMITY*

Nome e indirizzo della società / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Germania / *Germany* *SRN: DE-MF-000007705*

Dichiariamo sotto la nostra esclusiva responsabilità che /
We declare under our sole responsibility that

il dispositivo medico / *the medical device*	**Palapress vario**
Nome, tipo o modello, numero di lotto o di serie, eventualmente fonti e numero di articoli / *Name, type or model, batch or serial number, possibly sources and number of items*	Elenco degli articoli vedi allegato / *List of Articles see Annex*
Codice EMDN / *EMDN-Code* Codice GMDN / *GMDN code* Codice UMDNS / *UMDNS code* UDI-DI di base / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
di classe / *of class*	IIa
secondo la norma / *according to rule*	5-3, 19-3 secondo l'allegato VIII del regolamento sui dispositivi medici 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

soddisfa tutte le disposizioni del regolamento sui dispositivi medici 2017/745 ad esso applicabili. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Norme armonizzate applicate, norme nazionali o altri documenti normativi / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Palapress vario, Versione 2 *Further Applied standards see Technical Documentation of Product* Palapress vario*, Version 2*
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745 Allegato IX, Capitolo I, Paragrafi 2 e 3, e Capitolo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificato / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga / Germania CE 0197
Numero di registrazione / *Registration number*:	HZ 1198082-1
Numero versione / *Version number*	02
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Luogo, data / *Place, date*	Nome e funzione / *Name and function*

This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices. / La presente dichiarazione di conformità ha validità di 2 anni in relazione ai documenti di rilascio per il lotto corrispondente di dispositivi prodotti.

DEKLARACJA ZGODNOŚCI / *DECLARATION OF CONFORMITY*

Nazwa i adres firmy / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Niemcy / *Germany* *SRN: DE-MF-000007705*

Niniejszym deklarujemy pod rygorem odpowiedzialności, że / *We declare under our sole responsibility that*

wyrób medyczny / *the medical device*	**Palapress vario**
Nazwa, typ lub model, numer partii lub serii, ewentualnie źródła i liczba elementów / *Name, type or model, batch or serial number, possibly sources and number of items*	Wykaz wyrobów znajduje się w załączniku / *List of Articles see Annex*
Kod wyrobu wg EMDN / *EMDN-Code* Kod wyrobu wg GMDN / *GMDN code* Kod wyrobu wg UMDNS / *UMDNS code* Kod Basic UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
klasy / *of class*	IIa
zgodnie z regułą / *according to rule*	5-3, 19-3 zgodnie z załącznikiem VIII do Rozporządzenia 2017/745 w sprawie wyrobów medycznych / *according to Annex VIII of Medical Device Regulation 2017/745*

spełnia wszystkie przepisy Rozporządzenia 2017/745 w sprawie wyrobów medycznych, które go dotyczą. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Zastosowane normy zharmonizowane, normy krajowe lub inne dokumenty normatywne / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu Palapress vario, wersja 2 *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Procedura oceny zgodności wg. / *Conformity assessment procedure acc. to*	Rozporządzenie 2017/745 w sprawie wyrobów medycznych, załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Jednostka notyfikowana / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Niemcy CE 0197
Numer rejestracyjny / *Registration number*:	HZ 1198082-1
Numer wersji / *Version number*	02
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Miejscowość, data / *Place, date*	Imię i nazwisko, stanowisko / *Name and function*

Niniejsze deklaracja zgodności jest ważna przez 2 lata w połączeniu z dokumentami zwolnienia odpowiedniej partii wyprodukowanych wyrobów. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

DECLARAȚIE DE CONFORMITATE / *DECLARATION OF CONFORMITY*

Numele și adresa companiei / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Germania / *Germany* *SRN: DE-MF-000007705*

Declarăm pe propria răspundere că / *We declare under our sole responsibility that*

dispozitivul medical / *the medical device*	**Palapress vario**
Nume, tip sau model, număr de lot sau de serie, eventual sursele și numărul de articole / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de articole, vezi Anexa / *List of Articles see Annex*
Cod EMDN / *EMDN-Code* Cod GMDN / *GMDN code* Cod UMDNS / *UMDNS code* UDI-DI de bază / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
din clasa / *of class*	IIa
în conformitate cu regula / *according to rule*	5-3, 19-3 conform Anexei VIII la Regulamentul privind dispozitivele medicale 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

respectă toate prevederile Regulamentului privind dispozitivele medicale 2017/745 corespunzător. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Standarde armonizate, naționale aplicate sau alte documente normative / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Alte standarde aplicate, vezi documentația tehnică a Produsului Palapress vario, Versiunea 2 *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Procedură de evaluare a conformității în conf. cu / *Conformity assessment procedure acc. to*	Regulamentul privind dispozitivele medicale 2017/745, Anexa IX, Capitolul I, Secțiunile 2 și 3, și Capitolul III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organism notificat / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germania CE 0197
Numărul de înregistrare / *Registration number*:	HZ 1198082-1
Număr versiune / *Version number*	02
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023 Loc, dată / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nume și funcție / *Name and function*

Prezenta declarație de conformitate este valabilă timp de 2 ani împreună cu documentele de autorizare pentru respectivul lot de dispozitive produse. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

Názov a adresa spoločnosti / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Nemecko / *Germany* *SRN: DE-MF-000007705*

Vyhlasujeme na svoju výlučnú zodpovednosť, že / *We declare under our sole responsibility that*

zdravotnícka pomôcka / *the medical device*	**Palapress vario**
Názov, typ alebo model, číslo šarže alebo sériové číslo, prípadne zdroje a počet kusov / *Name, type or model, batch or serial number, possibly sources and number of items*	Zoznam položiek je uvedený v prílohe / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699eAU
triedy / *of class*	IIa
podľa pravidla / *according to rule*	5-3, 19-3 podľa prílohy VIII k nariadeniu 2017/745 o zdravotníckych pomôckach / *according to Annex VIII of Medical Device Regulation 2017/745*

spĺňa všetky ustanovenia nariadenia 2017/745 o zdravotníckych pomôckach, ktoré sa na ňu vzťahujú. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Použité harmonizované normy, národné normy alebo iné normatívne dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Ďalšie použité normy nájdete v technickej dokumentácii verzie 2 k produktu Palapress vario *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2*
Postup posúdenia zhody podľa / *Conformity assessment procedure acc. to*	prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaný orgán / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Nemecko CE 0197
Registračné číslo / *Registration number*:	HZ 1198082-1
Číslo verzie / *Version number*	02
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	29.03.2022
Hanau, Jan 4, 2023 Miesto, dátum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Meno a funkcia / *Name and function*

Toto vyhlásenie o zhode je platné 2 roky v súvislosti s dokumentmi o uvoľnení príslušnej šarže vyrobených pomôcok. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

KULZER

Artikelliste / *List of Articles*
Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt / *for the medical device*	**Palapress vario**
Versionsnummer Artikelliste/ *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	NA
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	02

UDI-DI / ***UDI-DI***	**Artikelnummer** / ***Article number***	**Name** / ***Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Ort, Datum / *Place, date*

i.V.
Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Name und Funktion / *Name and function*

Lista de artículos / *List of Articles*
Anexo / *Annex*: Declaración de conformidad / *Declaration of Conformity*

El producto sanitario / *The medical device*	**Palapress vario**
Número de versión / *Version number*	01
Sustituye al Anexo del / *Replaces Annex from*	NA
Esta lista de artículos es válida para la versión de la declaración de conformidad / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Lugar, fecha / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nombre y cargo / *Name and function*

Déclaration de conformité / *Declaration of Conformity*
Annexe / *Annex* : Liste des articles / *List of Articles*

Le dispositif médical / *The medical device*	**Palapress vario**
Numéro de version / *Version number*	01
Remplace l'annexe de / *Replaces Annex from*	NA
Cette liste d'articles est valable pour la déclaration de conformité, version / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Lieu, date / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nom et fonction / *Name and function*

Κατάλογος ειδών / *List of Articles*
Παράρτημα / *Annex*: Δήλωση συμμόρφωσης / *Declaration of Conformity*

Το ιατροτεχνολογικό προϊόν / *The medical device*	**Palapress vario**
Αριθμός έκδοσης / *Version number*	01
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	NA
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Τόπος, ημερομηνία / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Ονοματεπώνυμο και τίτλος / *Name and function*

Popis artikala / *List of Articles*
Dodatak / *Annex*: Izjava o usklađenosti / *Declaration of Conformity*

Medicinski proizvod / *The medical device*	**Palapress vario**
Broj verzije / *Version number*	01
Zamjenjuje Dodatak od / *Replaces Annex from*	NA
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Broj artikla / *Article number***	**Naziv / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Mjesto, datum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Ime i funkcija / *Name and function*

Elenco degli articoli / *List of Articles*
Allegato / *Annex*: Dichiarazione di conformità / *Declaration of Conformity*

Il dispositivo medico / *The medical device*	**Palapress vario**
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	NA
Questa lista di articoli è valida per la versione della dichiarazione di conformità / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Numero articolo / *Article number***	**Nome / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Luogo, data / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nome e funzione / *Name and function*

Lijst met artikelen / *List of Articles*
Annex / *Annex*: Verklaring van conformiteit / *Declaration of Conformity*

Het medisch hulpmiddel / *The medical device*	**Palapress vario**
Versienummer / *Version number*	01
Vervangt de bijlage van / *Replaces Annex from*	NA
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / *This article list is valid for the declaration of conformity version*	02

Unieke identificatiecode / *UDI-DI*	**Artikelnummer / *Article number***	**Naam / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Plaats, datum / *Place, date*

i.V Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Naam en functie / *Name and function*

Wykaz wyrobów / *List of Articles*
Załącznik / *Annex*: Deklaracja zgodności / *Declaration of Conformity*

Wyrób medyczny / *The medical device*	**Palapress vario**
Numer wersji / *Version number*	01
Zastępuje załącznik z dnia / *Replaces Annex from*	NA
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Numer wyrobu / *Article number***	**Nazwa / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Miejscowość, data / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Imię i nazwisko, stanowisko / *Name and function*

Listă de articole / *List of Articles*
Anexă / *Annex*: Declarație de conformitate / *Declaration of Conformity*

Dispozitivul medical / *The medical device*	**Palapress vario**
Număr versiune / *Version number*	01
Înlocuiește Anexa de la / *Replaces Annex from*	NA
Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Număr articol / *Article number***	**Nume / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Loc, dată / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nume și funcție / *Name and function*

Zoznam položiek / *List of Articles*
Príloha / *Annex*: Vyhlásenie o zhode / *Declaration of Conformity*

Zdravotnícka pomôcka / *The medical device*	**Palapress vario**
Číslo verzie / *Version number*	01
Nahrádza prílohu z / *Replaces Annex from*	NA
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Číslo položky / *Article number***	**Meno / *Name***
+J014647078630	64707863	Palapress vario, 80 ml DE/IT
+J014647078640	64707864	Palapress vario, 500 ml DE/GB/FR/NL
+J014660707350	66070735	Palapress vario, 500 ml IT/ES/GR/HR
+J014660946700	66094670	Palapress vario, 500 ml PL/RO/SK
+J014647139690	64713969	Palapress vario, 500 ml, JP
+J014647078700	64707870	Palapress vario, rosa, 100 g
+J014647078730	64707873	Palapress vario, farblos, 100 g
+J014647078790	64707879	Palapress vario, rosa, 500 g
+J014647078820	64707882	Palapress vario, farblos, 500 g
+J014647078890	64707889	Palapress vario, rosa, 1000 g
+J014647078900	64707890	Palapress vario, rosa opaque, 1000 g
+J014647078910	64707891	Palapress vario, rosa gead., 1000 g
+J014647078920	64707892	Palapress vario, farblos, 1000 g
+J014647078930	64707893	Palapress vario, R 50 gead., 1000 g
+J014647123430	64712343	Palapress vario, shade 200, 1000 g
+J014647124300	64712430	Palapress vario, rosa, 12000 g
+J014647147960	64714796	Palapress vario, light pink, 1000 g

Hanau, Jan 4, 2023

Miesto, dátum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Meno a funkcia / *Name and function*

DocuSign

Abschlusszertifikat

Umschlag-ID: 2ACB62104C9946EB8B2948E84CB12143
Status: Abgeschlossen
Betreff: Mit DocuSign abschließen: Mit_DocuSign_signieren_Palapress_vario_DoC V02_Annex V01.pdf
Quellumschlag:
Dokumentenseiten: 19
Signaturen: 19
Umschlagersteller:
Zertifikatsseiten: 5
Initialen: 0
Daniela Wienhold
Signatur mit Anleitung: Aktiviert
Leipziger Str. 2
Umschlag-ID-Stempel: Aktiviert
Hanau, Hessen 63450
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien
Daniela.Wienhold@kulzer-dental.com
IP-Adresse: 89.246.249.146

Eintragsverfolgung

Status: Original
03.01.2023 09:32:16
Inhaber: Daniela Wienhold
Daniela.Wienhold@kulzer-dental.com
Standort: DocuSign

Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com PRRC Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.190.65.37	Gesendet: 03.01.2023 09:37:00 Eingesehen: 04.01.2023 08:59:47 Signiert: 04.01.2023 09:00:13

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 04.01.2023 08:59:47
ID: a5ef97d0-7727-4c6b-b2f7-bc5dbc415e16

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

Bearbeiterversandereignisse	Status	Zeitstempel

Beauftragtenzustellereignisse	Status	Zeitstempel

Vermittlerversandereignisse	Status	Zeitstempel

Zertifizierter Versand - Ereignisse	Status	Zeitstempel

Kopienereignisse	Status	Zeitstempel
Anette Stadtfeld Anette.Stadtfeld@kulzer-dental.com Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	**Kopiert**	Gesendet: 03.01.2023 09:37:01

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Nicht über DocuSign möglich

Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	03.01.2023 09:37:01
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	04.01.2023 08:59:47
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	04.01.2023 09:00:13
Abgeschlossen	Sicherheitsprüfung ausgeführt	04.01.2023 09:00:13

Zahlungen	Status	Zeitstempel

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Kulzer GmbH (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Kulzer GmbH:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: dieter.lorber@kulzer-dental.com

To advise Kulzer GmbH of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at dieter.lorber@kulzer-dental.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Kulzer GmbH

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to dieter.lorber@kulzer-dental.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Kulzer GmbH

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to dieter.lorber@kulzer-dental.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Kulzer GmbH as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Kulzer GmbH during the course of your relationship with Kulzer GmbH.